

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. \_\_\_\_\_

b. DEVICES FDA 2891 NO. \_\_\_\_\_

c. DRUG FDA 2656 NO. \_\_\_\_\_

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)  
 SighlLife (also dba SighlLife Surgical Inc.)  
 2346 Jacksonville Road  
 Bethlehem, Pennsylvania 18017

a. PHONE 610-625-3800 EXT \_\_\_\_\_

b.  SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)

c.  TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)  
 SighlLife  
 Attn: Tom Miller  
 1200 6th Ave  
 Ste 300  
 Seattle, Washington 98101


7. ENTER CORRECTIONS TO ITEM 6

a. PHONE 206-838-4630 EXT \_\_\_\_\_

b. PHONE \_\_\_\_\_

8. U.S. AGENT

a. E-MAIL \_\_\_\_\_

9. REPORTING OFFICIAL'S SIGNATURE  


a. TYPED NAME Tom Miller

b. E-MAIL tom.miller@sighlLife.org

c. TITLE VP Quality Assurance/Regulatory Affairs

d. DATE 21-DEC-2016

**PART II - PRODUCT INFORMATION**

Types of HCT / Ps	Establishment Functions						11. HCT/PS DESCRIBED IN CFR 1271.10	12. HCT/PS MEDICAL DEVICES REGULATED AS BIOLOGICAL DRUGS	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store				
a. Bone										
b. Cartilage										
c. Cornea	X	X		X	X	X	X	X	X	
d. Dura Mater										
e. Embryo										
f. Fascia										
g. Heart Valve										
h. Ligament										
i. Oocyte										
j. Pericardium										
k. Peripheral Blood Stem										
l. Sclera	X	X		X	X	X	X	X	X	
m. Semen										
n. Skin										
o. Somatic Cell Therapy Products										
p. Tendon										
q. Umbilical Cord Blood										
r. Vascular Graft										
s. _____										
t. _____										
u. _____										
v. _____										